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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,359	11/29/2001	David J. Foran	UMNJ-P01-001	5528
28120	7590	01/10/2005	EXAMINER TABATABAI, ABOLFAZL	
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			ART UNIT 2625	PAPER NUMBER

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/998,359	Applicant(s) FORAN ET AL.	
	Examiner Abolfazl Tabatabai	Art Unit 2625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/28/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Claim Rejections - 35 USC § 102**

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, and 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Silver (U S 6,078,681).

Regarding claim 1, Silver discloses a system comprising:

a microscope (fig. 1 element 10) that provides an image of a biological specimen in digital form (column 1, lines 33-36), the microscope responsive to a control signal to change a parameter used to obtain the image of the biological specimen (column 13, lines 47-51 and column 15, lines 33-41), the parameter including at least one of an objective lens, a focus, a light level, and a specimen position (column 3, lines 60-65 and column 11, lines 66-67);

a database that includes one or more pathology profiles associated with one or more pathologies (column 7, lines 11-24), the one or more pathology profiles derived from images of one or more other biological specimens having one or more pathologies (column 15, lines 50-62);

a decision support system that processes the image from the microscope to obtain an image profile (column 10, lines 40-47), the image profile including descriptive data of the image (column 10, lines 40-50), the decision support system comparing the

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image profile to the one or more pathology profiles in the database to identify one or more of the one or more pathologies that are candidates for a pathology associated with the biological specimen (column 7, lines 11-24); and,

a client interface through which one or more remote users receive the image of the biological specimen and provide input to the system including at least one of generating the control signal to the microscope (column 3, lines 57-65), communicating with other ones of the one or more remote users (column 13, lines 25-31), and controlling operation of the decision support system (column 6, lines 43-64).

Regarding claim 2, Silver discloses the system of claim 1 wherein the microscope employs an auto-focusing algorithm that retains a history of one or more previous auto-focus settings (column 3, lines 57-65 and column 6, lines 54-64).

Regarding claim 3, Silver discloses the system of claim 1 further comprising an archival system which provides unsupervised image feature extraction and automated management of images of additional biological specimens for addition to the database (column 5, lines 8-12).

Claim 19, is similarly analyzed as claim 1 above.

Regarding claim 20, Silver discloses the method of claim 19, the server further configured to share the result and the image among a plurality of users (column 13, lines 24-31), and to forward electronic communications between two or more of the plurality of users (column 6, lines 43-64).

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Regarding claim 21, Silver discloses the method of claim 20 wherein the electronic communications include at least one of instant messaging, audio, text, or electronic mail (column 8, lines 1-10).

Regarding claim 22, Silver discloses the method of claim 19 further comprising: providing a microscope that provides an image of a biological specimen in digital form, the microscope responsive to a control signal to change a parameter used to obtain the image of the biological specimen (column 1, lines 33-36 and column 13, lines 47-51), the parameter including at least one of an objective lens, a focus, a light level, and a specimen position (column 3, lines 57-65); and,

providing a user interface through which one or more of a plurality of users (column 3, lines 60-65), connected to the client interface through a data network (column 3, lines 33-39), receive the image of the biological specimen and generate the control signal to the microscope (column 10, lines 40-49).

Regarding claim 23, Silver discloses the method of claim 22 wherein one of the plurality of users has a token that provides to the one of the plurality of users exclusive control over the control signal to the microscope (column 10, lines 40-49).

### **Claim Rejections - 35 USC § 103**

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 4, 5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silver (U S 6,078,681) in view of Spillert et al (U S 4,705,756).

Regarding claim 4, Silver is silent about the specific details regarding the system of claim 1 wherein the decision support system is trained using a ground truth database of images having independently confirmed pathologies.

In the same field of endeavor (medical image), however, Spillert discloses a method of determining the existence and /or the monitoring of a pathological condition in a mammal comprises confirmed pathologies (column 5, lines 64-68).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use confirmed pathologies as taught by Spillert in the system of Silver because Spillert provides Silver an improved method for determining effectiveness of a surgical procedure on a mammal to eradicate a pathologic state or condition or to detect recurrent disease.

Regarding claim 5, Silver discloses the system of claim 4 wherein the

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pathologies are independently confirmed using at least one of immunophenotyping, molecular studies, or gene expression (column 11, lines 61-64 and column 13, line 50).

Regarding claim 9, Silver is silent about the specific details regarding the system of claim 1 wherein the one or more pathologies include hematological disorders. In the same field of endeavor (medical image), however, Spillert discloses a method of determining the existence and /or the monitoring of a pathological condition in a mammal comprises hematological disorders (column 5, lines 14-23).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use hematological disorders as taught by Spillert in the system of Silver because Spillert provides Silver an improved method for determining effectiveness of a surgical procedure on a mammal to eradicate a pathologic state or condition or to detect recurrent disease.

**5.** Claims 6, 7 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Silver (U S 6,078,681) in view of Cabib et al (U S 5,991,028).

Regarding claim 6, Silver is silent about the specific details regarding the system of claim 1 wherein the decision support system compares the image profile to one of the one or more pathology profiles by quantitatively comparing a derived measure of shape, texture, and area for the image profile to a derived measure of shape, texture, and area for the one of the one or more pathology profiles. In the same field of endeavor (medical image), however, Cabib discloses spectral bio-imaging methods for cell classification comprises the decision support system compares the image profile to one of the one or more pathology profiles by quantitatively

comparing a derived measure of shape, texture, and area for the image profile to a derived measure of shape, texture, and area for the one of the one or more pathology profiles (column 23, lines 38-41).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use comparing a derived measure of shape, texture as taught by Cabib in the system of Silver because Cabib provides Silver an improved methods which can be used for automatic and /or semiautomatic spectrally resolved morphometric classification of cells. The methods also be used for classification of cells into grades, developmental stages, and to qualify and quantify metabolic processes within cells.

Regarding claim 7, Silver is silent about the specific details regarding the system of claim 6 wherein the derived measure of shape comprises a plurality of elliptical Fourier coefficients for an outline of a shape of one or more components of the biological specimen.

In the same field of endeavor (medical image), however, Cabib discloses spectral bio-imaging methods for cell classification comprises a plurality of elliptical Fourier coefficients (column 27, lines 51-58).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a plurality of elliptical Fourier coefficients as taught by Cabib in the system of Silver because Cabib provides Silver an improved methods which can be used for automatic and /or semiautomatic spectrally resolved



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morphometric classification of cells. The methods also be used for classification of cells into grades, developmental stages, and to qualify and quantify metabolic processes within cells.

Claim 24, is similarly analyzed as claim 6 above.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Silver (U S 6,078,681) and Cabib et al (U S 5,991,028) as applied to claim 6 above and further in view of Litt et al (U S 658,287 B1).

Regarding claim 8, Silver and Cabib are silent about the specific details regarding the system of claim 6 wherein the derived measure of texture is calculated using a multiscale simultaneous autoregressive model.

In the same field of endeavor (medical image), however, Litt discloses a system for predicting the onset of seizures based on features derived from signals indicative of brain activity comprises autoregressive model (column 11, lines 54-60).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a plurality of elliptical Fourier coefficients as taught by Litt in the system of Silver because Litt provides Silver an improved system which is implemented in an implantable device that an individual or physician can interface with in much the same manner as an implantable pacemaker or defibrillator.

7. Claims 10-12,14, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cabib et al (U S 5,991,028) in view of Grobet et al (U S 6,103,466).

Regarding claim 10, Cabib discloses a method comprising:

providing a database that includes one or more pathology profiles associated

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with one or more cells having one or more pathologies (column 22, lines 29-32), the pathology profile for each pathology including a shape measure derived from a shape of one or more cells associated with the pathology (column 23, lines 38-41), a texture measure derived from a texture of the one or more cells associated with the pathology, and an area measure derived from an area of the one or more cells associated with the pathology (column 23, lines 38-41);

receiving an image of a cell in digital form (column 15, lines 41-48).

However, Cabib is silent about the specific details regarding the steps of:

processing the received image to obtain a query vector that includes a shape measure of the cell in the received image, a texture measure of the cell in the received image, and an area of the cell in the received image; and,

comparing the query vector to the one or more pathology profiles in the database to obtain a quantitative measure of similarity between the cell in the received image and one of the one or more cells having one or more pathologies.

In the same field of endeavor (medical image), however, Grobet discloses double-muscling in mammals comprising the steps of:

processing the received image to obtain a query vector that includes a shape measure of the cell in the received image, a texture measure of the cell in the received image, and an area of the cell in the received image (column 13, lines 55-58); and,

comparing the query vector to the one or more pathology profiles in the database to obtain a quantitative measure of similarity between the cell in the received image and one of the one or more cells having one or more pathologies (column 13, lines 55-58).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use comparing the query vector to the one or more pathology profiles in the database as taught by Grobet in the system of Cabib because Grobet provides Cabib an improved system which is useful for the detection of a nucleotide sequence encoding a myostatin containing a first nucleic acid molecule based on nucleic-acid sequence located upstream of a mutation determined according to this system and a second nucleic acid molecule based on a nucleotide sequence located down-stream of the mutation.

Regarding claim 11, Cabib discloses the method of claim 10 further comprising suggesting a diagnosis for the cell in the received image based upon the quantitative measure of similarity (column 29, lines 31-37; column 30, lines 13-18 and column 35, lines 39-41).

Claim 12, is similarly analyzed as claim 10 above.

Regarding claim 14, Cabib discloses the method of claim 10 wherein processing the received image to obtain a query vector that includes a shape measure of the cell in the received image further comprises:

converting the image from a red-green-blue representation to a luminance-chrominance representation (column 11, lines 51-61); locating a plurality of coordinates of an outer boundary of at least one of the cell or one or more constituent components of the cell (column 11, lines 51-61); and, characterizing the outer boundary with a plurality of elliptical Fourier coefficients (column 27, lines 51-58).

Claims 17 and 18 are similarly analyzed as claim 10 above.

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8. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cabib et al (U S 5,991,028) and Grobet et al (U S 6,103,466) as applied to claim 10 above and further in view of Litt et al (U S 658,287 B1).

Regarding claim 15, Cabib and Grobet are silent about the specific details regarding the method of claim 10 wherein processing the received image to obtain a query vector that includes a texture measure of the cell in the received image further comprises selecting a plurality of overlapping windows within the received image and, for each one of the plurality of overlapping windows, calculating a texture at a plurality of resolutions.

In the same field of endeavor (medical image), however, Litt discloses a system for predicting the onset of seizures based on features derived from signals indicative of brain activity comprises selecting a plurality of overlapping windows within the received image and, for each one of the plurality of overlapping windows, calculating a texture at a plurality of resolutions (column 24, lines 33-38).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use overlapping windows as taught by Litt in the system of Cabib because Litt provides Cabib an improved system which is implemented in an implantable device that an individual or physician can interface with in much the same manner as an implantable pacemaker or defibrillator.

Regarding claim 16, Cabib and Grobet are silent about the specific details regarding the method of claim 15 further comprising applying a multiscale simultaneous autoregressive model.

In the same field of endeavor (medical image), however, Litt discloses a system for predicting the onset of seizures based on features derived from signals indicative of brain activity comprises autoregressive model (column 11, lines 54-60).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use autoregressive model as taught by Litt in the system of Cabib because Litt provides Cabib an improved system which is implemented in an implantable device that an individual or physician can interface with in much the same manner as an implantable pacemaker or defibrillator.

6. Claim 13, is rejected under 35 U.S.C. 103(a) as being unpatentable over Cabib et al (U S 5,991,028) and Grobet et al (U S 6,103,466) as applied to claim 10 above and further in view of Spillert et al (U S 4,705,756)

Regarding claim 13, Cabib and Grobet are silent about the specific details regarding the system of claim 1 wherein the one or more pathologies include hematological disorders.

In the same field of endeavor (medical image), however, Spillert discloses a method of determining the existence and /or the monitoring of a pathological condition in a mammal comprises hematological disorders (column 5, lines 14-23).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use hematological disorders as taught by Spillert in the system

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of Cabib because Spillert provides Cabib an improved method for determining effectiveness of a surgical procedure on a mammal to eradicate a pathologic state or condition or to detect recurrent disease.

### **Other Prior Art**

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Bacus et al (U S 5,016,283) disclose methods and apparatus for immunoploidy analysis.

Bevilacqua et al (U S 6,692,916 B1) disclose method and apparatus for Characterizing a biological condition or agent using precision gene expression profiles.

Kamentsky et al (U S 5,793,969) disclose network review and analysis of computer encoded slides.

Zakim et al (U S 5,733,739) disclose system and method for diagnosis of disease by infrared analysis of human tissues and cells.

### **Contact Information**

6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to ABOLFAZL TABATABAI whose telephone number is (703) 306-5917.

The Examiner can normally be reached on Monday through Friday from 9:30 a.m. to 7:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Mehta Bhavesh M, can be reached at (703) 308-5246. The fax phone number for organization where this application or proceeding is assigned is (703) 872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Abolfazl Tabatabai

Patent Examiner

Group Art Unit 2625

December 29, 2004

*A-Tabatabai*